AG

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY Dev

To:
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RECEIVED
14 JUN 2009
FILE No. 39833
G.E. EHRLICH (1995) LTD.

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 39833	Date of mailing (*day/month/year*) 01 JUN 2009 (d) **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/IL07/00918	International filing date (*day/month/year*) 19 July 2007 (19.07.2007)
Applicant SPECTRUM DYNAMICS	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer MARIA B. MARVICH Telephone No. (703) 308-0196

(See notes on accompanying sheet)

Form PCT/ISA/220 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 39833	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/IL07/00918	International filing date (*day/month/year*) 19 July 2007 (19.07.2007)	(Earliest) Priority Date (*day/month/year*)
Applicant SPECTRUM DYNAMICS		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the Report**
   a. With regard to the **language**, the international search was carried out on the basis of:
      ☒ the international application in the language in which it was filed.
      ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 Rule 43.6 *bis(a)*
   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.
2. ☒ **Certain claims were found unsearchable** (See Box No. II)
3. ☒ **Unity of invention is lacking** (See Box No. III)
4. With regard to the **title,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   ☒ the text is approved as submitted by the applicant.
   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. _____
      ☐ as suggested by the applicant.
      ☐ as selected by this Authority, because the applicant failed to suggest a figure.
      ☐ as selected by this Authority, because this figure better characterizes the invention.
   b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL07/00918

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 428-448,453-540 and 578-582
because they relate to subject matter not required to be searched by this Authority, namely:
Please See Continuation Sheet

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 290-295, 359, 362, 363, 367, 371, 372, 380-382, 384, 449-540, 578-582
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL07/00918

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61K 51/00**(2006.01);**A61N 5/00**(2006.01)

USPC: 424/1.11;604/403
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/1.11; 604/403

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
East dbases- USPAT, PGPUB, EPO, JPO, Derwent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 20060160157 (ZUCKERMAN, M.M.) 20 July 2006 (20.07.2006), para 144	273, 274, 276
y	US 20050205792 (RUOSSO et al) 22 September 2005 (22.09.2005), firgure 5, 7 and para 0086	283-286, 289
X	US 20070166227 (LIU et al) 19 July 2007 (19.07.2007),para 139, 233	254-261, 267, 385-388, 566
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Y		283-286, 289
X	US 20050020915 (BELARDINELLI et al) 27 January 2005 (27.01.2005), para 242	541, 552, 583, 584, 586, 587
X	US 20040086437 (JACKSON et al) 6 May 2004 (06.05.2004), see abstract, para 0004	252, 253

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
01 September 2008 (01.09.2008)	01 JUN 2009
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer MARIA B. MARVICH Telephone No. (703) 308-0196

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL07/00918

Box II Observations where certain claims were found unsearchable 1. because they relate to subject matter not required to be searched by this Authority, namely:

because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

BOX III. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I-LXXXIII, claims 1-251 and 566-577, drawn to methods of 83 distinct methods of radioimaging as set forth in tables 1-83 wherein the methods require administration of radiopharmaceuticals followed by radioimaging the target organ.

Groups LXXXIV-CXLIV, claim 252, drawn to 60 distinct methods of packaging a pharmaceutical comprising packaging any one of 60 distinct radiopharmaceuticals.

Group CXLV-CCV, claim 253, drawn to any one of 60 distinct packaged radiopharmaceuticals.

Group CCVI, claims 254-272, drawn to a radiopharmaceutical have a dose equivalent of 2.5 mrem or less per kg body weight or 150 mrem or less.

Group CCVII-CCCLXVIII, Claims 273-276, drawn to one of approximately 162 radiopharmaceuticals that are in low dose

Group CCCLXIX, Claims 283-289, 296-331, 339-358, 360, 361, 364-366, 368-370, 373-379, 383, drawn to methods of radioimaging the heart comprising administering a low dose of a first and/or a second pharmaceutical followed by acquiring date representing a distribution of the first pharmaceutical

Group CCCLXX, Claims 283-284, 332-335, 368-370, 373-379, 383 drawn to methods of radioimaging the lung comprising administering a low dose of a first pharmaceutical followed by acquiring date representing a distribution of the first pharmaceutical

Group CCCLXXI, Claims 283-284, 336-338, 368-370, 373-379, 383 drawn to methods of radioimaging the bone comprising administering a low dose of a first pharmaceutical followed by acquiring date representing a distribution of the first pharmaceutical

Groups CCCLXXII-CCCLLXLII, Claims 385-427, drawn to any of 20 distinct kits comprising a first and second radiopharmaceutical wherein the 20 kits are found in claims 388, 390, 392, 394, 396, 398, 400, 402, 404, 406, 408, 410, 412,414, 416, 418, 420, 422, 424, 426.

Group CCCXCIII, Claims 541-565 and 583-588, drawn to a diagnostic pharmaceutical kit comprising a first and/or second radiopharmaceutical with saline and/or a pharmacological stress agent and methods of using.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL07/00918

The inventions of Groups I-LXXXXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the "special technical feature" of claims 1-251 and 566-577 is the step of administering a radiopharmacetucial followed by radioimaging, which as shown by Lui et al (see e.g. claim 44) lacks novelty of inventive step and does not make a contribution over the art.

Each of Groups LXXXIV-CXLIV is drawn to methods of packaging structurally and functionally distinct compounds that do not share a common structural feature. And as the methods are drawn to processes that require distinct products, the methods themselves are distinct in that distinct products are used in the methods and distinct products are the result of the methods. Groups I-LXXXXIII and Groups LXXXIV-CXLIV do not share any method steps and therefore comprise distinct methods and steps.

Each of Groups CCVII-CCCLXVIII do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The "special technical feature" of Groups CCVII-CCCLXVIII is a low dose radiopharmaceutical, which is shown by Zuckerman (20060160157, see para 144), to lack novelty of inventive step and does not make a contribution over the prior art.

Groups CCCLXIX-CCCLXXI do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The "special technical feature" of Groups CCVII-CCCLXVIII is a low dose radiopharmaceutical that is administered followed by acquiring date representing distribution of the at least first radiopharmaceutical, which is shown by Liu et al (see 20070166227 for PCTUS0504872, see e.g. para 233) in view of Ruosso et al (20050205792, see figure 5 and para 0086), to lack novelty of inventive step and does not make a contribution over the prior art.

Groups CCCLXXII-CCCLLXLII do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The "special technical feature" of Groups CCVII-CCCLXVIII is a kit comprising two radiopharmaceuticals, which is shown by Liu et al (see 20070166227 for PCTUS0504872, see e.g. para 139), to lack novelty of inventive step and does not make a contribution over the prior art.

Group CCCXCIII, does not relate to a single general inventive concept with any of Groups I- CCCXCII because they lack the same or corresponding technical feature. The "special technical feature" of Group CCCXCIII is a kit comprising two radiopharmaceuticals, which is shown by Belardinelli et al (US 20050020915; see para 242), to lack novelty of invention and does not make a contribution over the prior art.